

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

INFORMED CONSENT ACTION NETWORK and
THE INSTITUTE FOR AUTISM SCIENCE,

Plaintiffs,

-against-

XAVIER BECERRA, in his capacity as the Secretary of
the United States Department of Health and Human
Services,

Defendant.

COMPLAINT

JURY TRIAL DEMANDED

The above-captioned Plaintiffs, through their undersigned counsel, as for their Complaint against the above-captioned Defendant allege as follows:

INTRODUCTION

1. The National Childhood Vaccine Injury Act of 1986 (the “**Act**”) (42 U.S.C. § 300aa-1, *et seq.*) provides immunity to pharmaceutical companies for injuries caused by their vaccine products and shifts the responsibility to assure vaccine safety to the Secretary of the United States Department of Health & Human Services (the “**Secretary**”). Those responsibilities include, *inter alia*, that “the Secretary shall ... make or assure improvements in ... the licensing, ... testing, labeling, [and] warning, ... of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines” as well as “develop and disseminate vaccine information materials ... based on available data and information.” 42 U.S.C. § 300aa-26 and 300aa-27.

2. The Act provides that “any person may commence in a district court of the United States a civil action on such person’s own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.” 42 U.S.C. § 300aa-31. The

Plaintiffs commence this action for the Secretary's failure to perform certain acts and duties pursuant to the Act which have caused direct and specific injuries to Plaintiffs.

3. The Informed Consent Action Network (“**ICAN**”) is an organization dedicated to improving vaccine safety through, *inter alia*, investigating and disseminating information underpinning the scientific support for the safety of childhood vaccines in order to address any gaps and strengthen the safety profile of the childhood vaccine schedule. The Institute for Autism Science (“**IAS**”) is involved in supporting families that have a child with autism spectrum disorder (“**autism**”), as well as supporting research to identify the causes of autism in order to better understand how to treat and prevent autism (the IAS together with ICAN, the “**Plaintiffs**”).

4. In the past four decades, no claim regarding vaccination has received more attention and publicity than the claim that vaccines cause autism. Likewise, federal health authorities claim to have studied vaccines and autism more thoroughly than any other type of alleged vaccine injury. Federal health authorities assert that studies establish that vaccines do not cause autism.

5. Reflecting this conclusion, the Center for Disease Control and Prevention (“**CDC**”) unequivocally asserts on its website that “Vaccines Do Not Cause Autism”:



Various CDC department heads have also testified before Congress and declared on national news outlets that vaccines do not cause autism. Given the CDC's reputation as the premiere authority on vaccinations globally, this five-word pronouncement has global implications, including on the

allocation of billions of dollars of scientific funding for research into the causes of autism, treatments for autism, and research priorities regarding vaccines.

6. Despite the unequivocal assertion by the CDC that vaccines do not cause autism, and the beating of this assertion into the minds of the public for decades, numerous peer-reviewed articles report that a majority of parents of children with autism have reported and continue to report one or more vaccines, including DTaP, Hepatitis B, Hib, PCV13, and IPV, as a cause of their child's autism. Each of these vaccines are injected into babies 3 times during the first 6 months of life pursuant to the CDC's childhood vaccine schedule.

7. In 1986, when the Act was passed, the only vaccine injected into babies before one year of age was a pertussis-containing vaccine. Due to parental complaints in the early 1980s that this vaccine caused their child's autism, Congress, via the Act, required the Secretary to commission the Institute of Medicine ("**IOM**") to "review of all relevant medical and scientific information ... on the ... extent of the relationship, if any, between vaccines containing pertussis ... and ... Autism." The IOM issued its report in 1991 and explained that it could not identify any studies addressing pertussis-containing vaccines and autism. (*Infra* § III.a. ¶ 51)

8. Despite the confirmed absence of any scientific information about the relationship between pertussis-containing vaccines and autism, neither the Secretary nor the CDC took any action to conduct such studies. Indeed, twenty-one years later, the IOM was again commissioned by the federal health authorities to conduct this same assessment because, according to the federal health authorities, autism remained one of the most commonly claimed injuries from this vaccine. The IOM's report in 2012 found only one study that looked at the issue of pertussis-containing vaccines and autism, and that study *did* find a link between this vaccine and autism. As with

pertussis vaccines, the IOM also found no studies to support that tetanus vaccine and diphtheria vaccine do not cause autism. (*Infra* § III.b. ¶ 56)

9. In 2014, an agency within HHS again found that there are no studies supporting a claim that these three vaccines do not cause autism and the agency was also unable to identify a study to support the assertion that Hepatitis B vaccines do not cause autism. Rather, it found only one study regarding Hepatitis B and autism and that study found that babies receiving this vaccine had autism at three times the rate as those not receiving this vaccine. (*Infra* § III.c. ¶ 61)

10. The Plaintiffs also could not find a single study to support the CDC's conclusion that vaccines given to babies do not cause autism -- and, in fact, could only find studies supporting the contrary conclusion, *i.e.*, that there is a link between vaccines and autism. Given the CDC's clear and unequivocal statements on this issue, the Plaintiffs nonetheless hoped the Secretary and CDC could identify studies which support the conclusion that the vaccines given to babies do not cause autism.

11. ICAN, therefore, sent a demand – subscribed to by 55 organizations whose members exceed 5 million Americans – to the Secretary pursuant to 42 U.S.C. § 300aa-31 on October 12, 2017 stating that “there are ... no published studies showing that autism is not caused by Hepatitis B, Rotavirus, Hib, Pneumococcal, Inactivated Poliovirus, Influenza, Varicella, or Hepatitis A vaccines – all of which HHS recommends babies receive, typically multiple times, by one year of age.” The demand therefore asked the Secretary to “confirm that HHS shall forthwith remove the claim that ‘Vaccines Do Not Cause Autism’ from the CDC website, or alternatively, please identify the specific studies on which HHS bases its blanket claim that no vaccines cause autism.” (*Infra* § III.e. ¶ 65)

12. The Secretary responded on January 1, 2018 but failed to identify any studies that support the assertion that vaccines given to babies do not cause autism. ICAN has sent numerous unrequited follow-up requests to the Secretary asking for this science. (*Infra* § III.g. ¶ 70)

13. In light of the Secretary's failure to produce scientific studies, the Plaintiffs went directly to the CDC, the very agency making the unequivocal assertion. The Plaintiffs submitted requests pursuant to the Freedom of Information Act ("FOIA") on June 21, 2019 requesting that the CDC produce the studies it relies upon to claim that vaccines injected into babies do not cause autism. (*Infra* § III.i. ¶ 73)

14. When the CDC failed to provide any studies responsive to these requests, the Plaintiffs commenced an action against the CDC on December 31, 2019, captioned *Institute for Autism Science, et al. v. Centers for Disease Control and Prevention*, No. 19-cv-11947 (S.D.N.Y.). The action requested that the Court enter an order requiring the CDC to provide the studies it relies upon to claim that the vaccines given during the first year of life do not cause autism or, in the alternative, to admit that it has no such studies. The CDC finally identified, in a stipulated order entered on March 2, 2020, a total of 16 studies and 4 reviews (*i.e.*, a review of studies on a given topic) that it relies on to claim that the vaccines given to babies do not cause autism. **Not one of these studies or reviews supports the claim that vaccines injected into babies – DTaP, Hep B, Hib, PCV13, and IPV – do not cause autism.** Instead, these studies/reviews include:

- 1 study concerning MMR (not a vaccine about which ICAN inquired);
- 13 studies concerning thimerosal (not an ingredient in any vaccine about which ICAN inquired);
- 3 reviews and 1 study concerning both MMR and thimerosal;
- 1 study concerning antigen (not vaccine) exposure; and
- 1 review concerning MMR, thimerosal, and DTaP.

15. Only one of the studies or reviews listed by the CDC concerned a vaccine given to babies. This was a 2012 review by the IOM, described above, paid for by the CDC, which

conducted a comprehensive review looking specifically for studies relating to DTaP and autism. The IOM concluded that it could not identify a single study to support that DTaP does not cause autism. Instead, the only relevant study the IOM could identify **found an association** between DTaP and autism. In other words, the only study identified by the CDC in the court ordered stipulation that actually reviewed a vaccine given to babies found that there is nothing supporting the CDC's claim that DTaP does not cause autism. (*Infra* § III.j. ¶ 79)

16. Dumbfounded by this response, the Plaintiffs submitted another FOIA request on March 10, 2020 for “All studies supporting the claim that DTaP does not cause autism,” giving yet another chance for the CDC to provide studies to support its public assertion. In this way, the Plaintiffs asked for any studies that *support* that DTaP does not cause autism regardless of whether or not the CDC *relies upon* each one. On March 23, 2020, the CDC responded to this FOIA request by pointing to the same unresponsive and inadequate list of twenty studies it had previously pointed to in the stipulation and order of March 2, 2020. (*Infra* § III.k. ¶ 82)

17. On March 27, 2020, ICAN provided the CDC yet another opportunity to provide supportive studies for the claim still being shared with the public by submitting yet another FOIA request, this time for: “Studies created or retained by CDC to support the claim that DTaP does not cause autism.” The CDC again responded by pointing to the same list of twenty studies and reviews, all of which either relate to MMR or thimerosal, a single antigen (not vaccine) study, and one review by the IOM that looked for any support that DTaP does not cause autism and could not find a shred of such evidence. (*Infra* § III.k. ¶ 83)

18. On the heels of the foregoing, the CDC finally removed the claim that “Vaccines Do Not Cause Autism” from its webpage on August 27, 2020. Nearly five months later, on January 21, 2021, ICAN widely publicized that the CDC had removed the statement “Vaccines Do Not

Cause Autism” from its webpage. Within days, the CDC restored this claim to its vaccine-autism page. (*Infra* § III.1. ¶¶ 84-85)

19. The claim by the Secretary and the CDC that “Vaccines Do Not Cause Autism” has massive implications for the over 1 million children in the United States with autism and the 13.8 million children expected to be diagnosed with autism in the coming five years. Whether vaccines do or do not cause autism should be determined through scientific inquiry. Groups engaged in finding therapies for autism are regularly hampered by not knowing the etiology of this condition. Normally, scientific inquiry into unknown etiologies involves conducting studies that either show a link between a condition and a cause, or ruling out such a link. But so long as the CDC claims that vaccines do not cause autism, despite not having the science to support that claim, the necessary scientific inquiries will never receive the funding or the attention they deserve.

20. The Secretary’s refusal to engage in the research needed to declare whether vaccines cause autism and his grant of permission to the nation’s health agencies to claim that vaccines do not cause autism, without the requisite scientific support, stifles the needed research to determine whether vaccines given to babies do not cause autism. This creates concrete harms to Plaintiffs as detailed *infra* at IV and is a direct violation of his obligation under the Act which provides, *inter alia*, that “the Secretary shall ... make or assure improvements in ... the licensing, ... testing, labeling, [and] warning, ... of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines” as well as “develop and disseminate vaccine information materials ... based on available data and information.”

21. Plaintiffs, therefore, bring this action pursuant to the Act’s provision that “any person may commence in a district court of the United States a civil action on such person’s own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or

duty under this part.” 42 U.S.C. § 300aa-31. Plaintiffs seek a declaration that the Secretary has violated his duties pursuant to 42 U.S.C. § 300aa-26 and 42 U.S.C. § 300aa-27 by asserting that “vaccines do not cause autism” without possessing scientific studies supporting that vaccines given to babies do not cause autism, and an order that the Secretary shall henceforth remove, and cause all agencies under the Secretary’s direct or indirect control to remove, from any public facing communications, the assertion that “vaccines do not cause autism” until such time as the Secretary can show to the Court’s satisfaction that the Secretary possesses scientific studies that specifically support that the vaccines given to babies (*i.e.*, under one year of age) do not cause autism.

PARTIES

22. Many national and international Plaintiffs have expressed strong support for this action but did not participate out of fear that the funding they receive to support children with autism from federal and state health authorities, as well as corporate sponsors, would be terminated.

23. Plaintiff Informed Consent Action Network is a not-for-profit organization with an office located at 140 Broadway, 46th Floor, New York, New York 10005. Plaintiff Institute for Autism Science is a not-for-profit organization with an office located in Villa Park, California.

24. Defendant is the Secretary (the “**Secretary**”) of the United States Department of Health and Human Services (“**HHS**”), a department within the Executive Branch of the United States Government and an agency within the meaning of 5 U.S.C. § 552(f).

JURISDICTION AND VENUE

25. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to same and 28 U.S.C. § 1391(a).

BACKGROUND & FACTS

I. National Childhood Vaccine Injury Act of 1986

26. Unlike virtually every other company selling a consumer product, pharmaceutical companies are not liable for injuries caused by their vaccine products. The National Childhood Vaccine Injury Act of 1986 (42 U.S.C. §§ 300aa-1 through 300aa-34) effectively grants pharmaceutical companies immunity from financial liability for injuries caused by their vaccine products and instead places the responsibility for vaccine safety in the hands of the Secretary.

a. Manufacturers Faced Enormous Liability for Vaccine Injuries

27. Product liability attorneys provide a critical check in ensuring that unsafe products are improved or eliminated from the market through civil lawsuits. By the mid-1980s, pharmaceutical companies were facing crippling liability from their vaccine products due to lawsuits brought by parents whose children were injured by these products. *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227 (2011) (“by the mid-1980’s ... the remaining manufacturer [of diphtheria, tetanus and pertussis vaccine] estimated that its potential tort liability exceeded its annual sales by a factor of 200”). The result was that by 1986 the “litigation costs associated with claims of damage from vaccines had forced several companies to ... stop producing already licensed vaccines” and the remaining pharmaceutical companies producing vaccines threatened to withdraw from the vaccine market. IOM, *Adverse Events Associated with Childhood Vaccines*, (1994) at 2.

28. Instead of permitting market forces to drive pharmaceutical companies to develop safer vaccines – as occurs with drugs and almost all other consumer products – in 1986, Congress passed the National Childhood Vaccine Injury Act, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the “Act”), which virtually eliminated economic liability for pharmaceutical companies

for injuries caused by their vaccine products. *See* 42 U.S.C. § 300aa-11 (“No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death.”); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (“we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects”).

29. Since 1983, the childhood vaccine schedule for babies (*i.e.*, before 1 year of age) has grown from 3 injections of just 1 vaccine (DTP) to 17 injections of 6 vaccines (Hep B, DTaP, Hib, PCV13, IPV, IIV). In this same timeframe, the childhood vaccine schedule has overall (*i.e.*, 18 years or younger) grown from 7 injections of just 2 vaccines (DTP & MMR) to 50 injections of 12 vaccines (Hep B, DTaP, Hib, PCV13, IPV, IIV, MMR, VAR, Hep A, Men, Tdap, and HPV).

30. During that time, with a liability-free, captive market of over 60 million children required to receive these vaccines by state law, vaccine sales have similarly grown from just a few hundred million dollars around 1986 to over \$37 billion in 2020. <https://files.eric.ed.gov/fulltext/ED255480.pdf>; <https://tinyurl.com/3x3k977r>.

b. The Secretary Becomes Singularly Responsible for Vaccine Safety

31. By granting manufacturers immunity from actual or potential liability for injuries caused by vaccines, Congress eliminated the market forces relied upon to assure safety. Recognizing it eliminated the incentive for pharmaceutical companies to assure the safety of their vaccine products, Congress made the Secretary directly responsible for vaccine safety.

32. The Secretary’s mandate to assure the safety of vaccines is codified at 42 U.S.C. § 300aa-27, titled “**Mandate for safer childhood vaccines**” (the “**Mandate**”). The Mandate underpins all vaccine safety in the United States. It provides:

- (a) **General rule.** ... [T]he Secretary shall — (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions ... and (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to ... licensing, ... testing, labeling, [and] warning, ... of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.
- (b) **Task force.** The Secretary shall establish a task force on safer childhood vaccines which ... shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).
- (c) **Report.** Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to ... the House and ... Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

33. The requirements of the Mandate, however, are only effective if the Secretary implements them. The Task Force required by part “b” of the Mandate was disbanded in 1998, and the Secretary has not prepared or filed a single biennial vaccine safety report for Congress as required by part “c” of the Mandate. *Informed Consent Action Network v. United States Department of Health and Human Services*, 18-cv-03215-JMF, (Doc # 18) (S.D.N.Y. July 9, 2018).

c. The Secretary’s Serious Conflicts in Fulfilling Vaccine Safety Duties

34. While the Secretary has been derelict in his duties under the Mandate, the Secretary has vigorously fulfilled other obligations under the Act, including to increase vaccine uptake and to defend against legal claims that a vaccine caused an injury.

35. As for vaccine uptake, HHS spends over \$5 billion annually promoting and purchasing vaccines. See <https://www.hhs.gov/about/budget/index.html>. It also maintains extensive

programs working with manufacturers, state and local officials to assist in mandating vaccines, eliminating exemptions, and otherwise increasing vaccine uptake.

36. As for defending claims of vaccine injury in court, the Act established the Vaccine Injury Compensation Program (“**Vaccine Court**”), which is part of the U.S. Court of Federal Claims. Congress intended for the Vaccine Court to serve as a way to compensate people injured by vaccines. <https://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters>. If an individual is injured by a vaccine, he or she must bring a claim in the Vaccine Court. The Secretary is the respondent in Vaccine Court and is legally obligated to defend against any claim that a vaccine causes injury. 42 U.S.C. § 300aa-12 (“In all proceedings brought by the filing of a petition [in Vaccine Court] the Secretary shall be named as the respondent.”)

37. In the Vaccine Court, the Secretary is represented by the formidable resources of the U.S. Department of Justice (“**DOJ**”) and vigorously defends against any claim that a vaccine has caused injury. *See, e.g.,* <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf>. (“DOJ attorneys make full use of the apparently limitless resources available to them,” “pursued aggressive defenses in compensation cases,” “establish[ed] a cadre of attorneys specializing in vaccine injury” and “an expert witness program to challenge claims.”)

38. Hence, the Secretary, while responsible for vaccine safety, is simultaneously responsible for the conflicting duty of defending against claims of vaccine injuries. Any study or assertion by HHS or its agencies, including the CDC, which reflects that a vaccine already on the market causes a harm can and will be used against the Secretary in Vaccine Court to establish liability. For example, if a single study conducted by HHS shows that even 1 in 5 cases of autism are caused by vaccines, it would result in approximately \$1.3 trillion in liability. Nonetheless, the

Act makes the Secretary responsible for performing or assuring the performance of studies to assess what injuries are caused by vaccines.¹

II. Autism

39. Autism spectrum disorder (“**autism**”) is a condition diagnosed by meeting certain criteria outlined in the Diagnostic and Statistical Manual of Mental Disorders, currently in its fifth edition (the “**DSM-5**”). The criteria require finding:

- (i) persistent deficits in social communication and social interaction across multiple contexts;
- (ii) restricted, repetitive patterns of behavior, interests, or activities;
- (iii) symptoms cause clinically significant impairment in social, occupational, or other important areas of current functioning;
- (iv) symptoms present in early developmental period; and
- (v) these disturbances are not better explained by intellectual disability or global developmental delay.

All of five of these criteria must be met and present for a child to be diagnosed with autism.

40. Among the children that meet these criteria and receive an autism diagnosis, in addition to the foregoing, an estimated 68 percent engage in aggressive behaviors toward caregivers, 40 percent are nonverbal, 30 percent exhibit self-injurious behavior with head banging, arm biting and skin scratching being the most common, and 28 percent wander or bolt from safety.

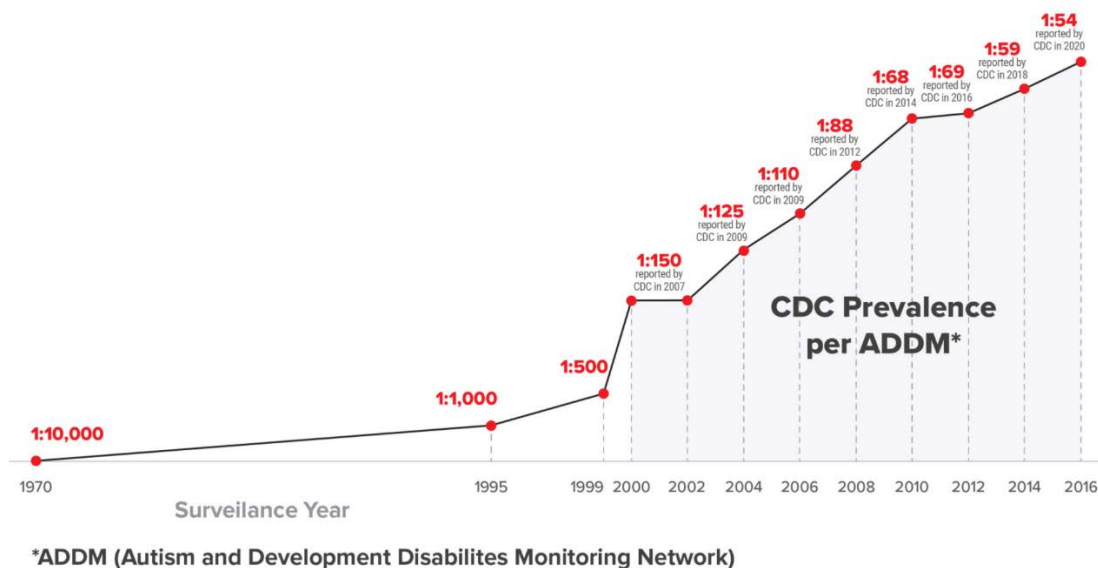
The following is a popular meme circulated within groups of parents with children of autism:

Every parent plans to raise their child for about 18 years, set them free for 30 years and then hope they come back to help them face the final years of their own life. A SPECIAL NEEDS parent plans to raise their child for 65 years and while doing so also has to prepare for the other 20 or so after they themselves are long gone. . . . Let that

¹ It is therefore critical that the safety of these vaccine products be established prior to licensure, but as the U.S. House Committee on Government Reform has found, the “overwhelming majority of members” of the CDC and FDA’s vaccine committees have conflicts of interest because of “substantial ties to the pharmaceutical industry,” and that these committees reflect “a system where government officials make crucial decisions affecting American children without the advice and consent of the governed.” <https://www.icandecide.org/wp-content/uploads/2021/04/OGR-Majority-Report.pdf>.

sink in for just a moment and you will begin to understand the drive and determination that many of us have while we are here on Earth.

41. Since the 1980s, the rise in cases of autism has occurred in lock-step across the United States without any concentration in any particular geographical area, *see* the CDC's Autism and Developmental Disabilities Monitoring (ADDM) Network <https://www.cdc.gov/ncbddd/autism/addm.html>, the U.S. Department of Education data collected pursuant to the Individuals with Disabilities Act (IDEA) <https://sites.ed.gov/idea/data/>, the California Department of Developmental Services (CDDS) <https://www.dds.ca.gov/transparency/autism/>:



Autism rates have also risen in lockstep across all racial groups, ethnic groups, and religious groups.

42. The cause of autism is an environmental change that has occurred throughout the United States. A study published in the Environmental Health by a researcher from the University of Colorado titled *A comparison of temporal trends in United States autism prevalence to trends in suspected environmental factors* reviewed the correlations between numerous environmental factors suspected of potentially causing autism and the change in the level of their exposure during

childhood since the 1980s. <https://pubmed.ncbi.nlm.nih.gov/25189402/>. The environmental exposure in the study showing the highest statistical correlation with autism rates was the increasing doses of vaccination. The following charts are from this study. The red line represents the number of vaccine doses and the blue line represents the rate of autism:

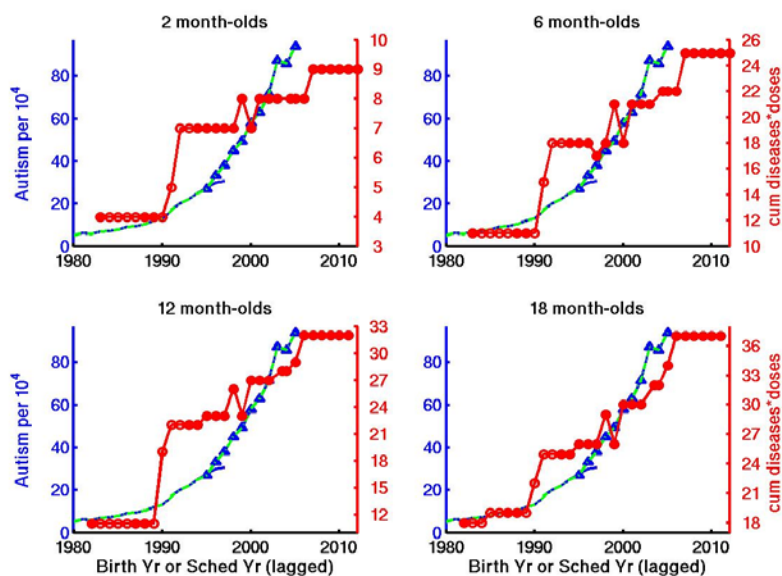


Figure S8. Temporal trend in autism compared to temporal trend in cumulative number of immunizations administered to U.S. infants and toddlers by 2,6,12 and 18 months via immunization according to the CDC recommended schedule. The immunization curves are lagged by milestone age rounded down to nearest year (i.e., 0,0,1, and 1 years, respectively).

43. Correlation does not equal causation, but it does, in this instance, provide a strong safety signal that merits investigation. Indeed, ruling out vaccines as a cause of autism was and remains important because there is an abundance of science, including from the National Institutes of Health (“**NIH**”), which demonstrates that autism’s etiology may result from dysfunction in the immune system, that autism cases rose alongside a rise in the childhood vaccine schedule, and that vaccines are intended to and do systemically modify the immune system.

44. Moreover, thousands of parents have provided video and/or written testimony sharing that they witnessed their child fall ill immediately after vaccination, then regressed, and

subsequently received an autism diagnosis. Copies of these videos and testimonies can be provided to the Court upon request. This alone, of course, does not mean vaccines cause autism but it is true that vaccines are the most common environmental factor to which parents of autistic children point as causing their child's autism based on their parental experience with their child.

45. The response from federal health authorities has not been a serious and respectful effort to investigate such a significant number of materially similar observations. Instead, when a parent – whose experience is that their child developed autism from vaccination – tries to inform a medical professional, the media, and others of same, that parent is immediately branded an “activist,” a “conspiracy theorist,” and, more recently, cancelled from social media. The calls by this community for the study of vaccines and autism has not been heeded. The response has been ad homonym rather than scientific.

46. A total of 158,105 adults (18 years and older) with autism received social security income while there are currently over one million children with autism. As these children enter adulthood, they will add a crushing burden on the social security services system which will begin paying many of them benefits for life starting at age 18. Indeed, adults with autism represented 1.3% of first-time social security income given to adults in 2005 but represented 5% in 2015. Individuals with autism represents only a small fraction the approximately 1.5 million adults with intellectual disabilities receiving supplemental income through social security. By 2040, in 19 short years, it is estimated that there will be 5 million additional adults with autism that will be added to the social security system in addition to those that have intellectual disabilities for other reasons. Not only will this create a potentially breaking strain on this system, but the infrastructure to handle this surge in autistic adults – 80 percent male, mostly young and physically strong, often aggressive, and with relatively little capacity for productive work – is nonexistent today.

47. One conservative estimate of the lifetime cost of a disabled person puts the number at \$1.9 million. If we apply that number to the projected 7 million (5 million adults plus about 2 million children) autistic individuals in the United States in 2040, that yields a total lifetime cost of that new autistic population of around \$13.3 trillion. That is approximately triple the entirety of the current federal budget. That amount also does not account for the lost opportunity cost to society. Identifying the environmental cause of autism is a national emergency and ruling out vaccines as a cause is urgent.

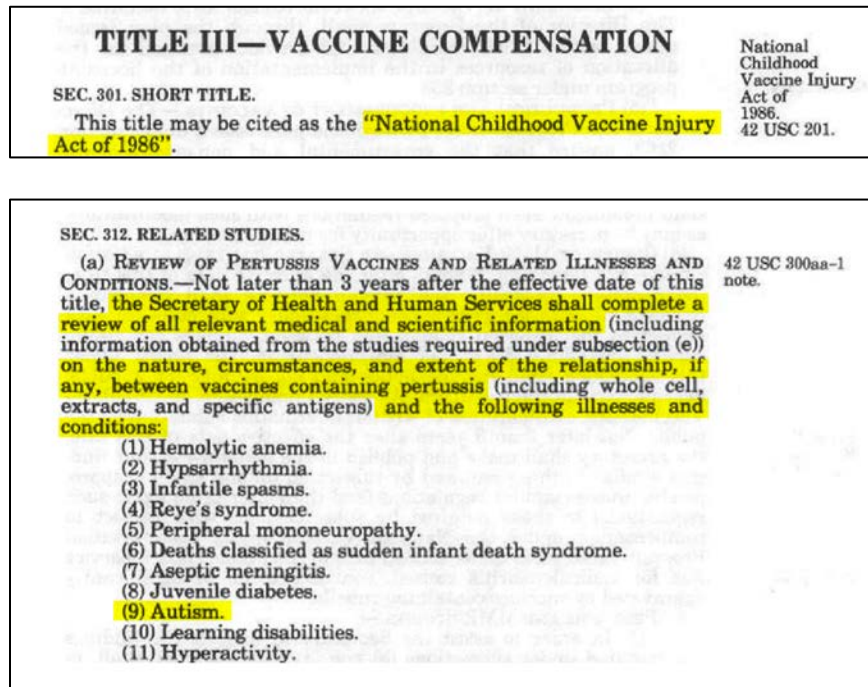
48. Unfortunately, instead of scientifically investigating whether vaccines given to babies cause autism, federal health authorities have instead squandered federal money to engage in a public relations campaign. Federal health authorities routinely publish studies regarding vaccines and potential vaccine harms using health care data systems available to them, but not to the public. These systems could easily be used to compare the autism rate between children that have been vaccinated with those that have not received any vaccines. Whether federal health authorities have conducted this simple review is unknown. What is known is that no such study has ever been published by federal health authorities.

III. The Secretary Makes the Unsupported Claim That Vaccines Given to Babies Do Not Cause Autism

49. In 1986, the only vaccine the CDC recommended for routine injection into babies (an infant below the age of 1 year) was a pertussis-containing vaccine (DTP or DTaP). The number of CDC recommended routine injections into babies steadily increased after the passage of the Act in 1986 until it reached the current 16 doses of six vaccines during the first six months of life.

a. **In 1986, Congress Directed the Secretary to Review Whether Pertussis Vaccines Cause Autism**

50. The concern that pertussis-containing vaccines could cause autism was identified by Congress as a research priority in the Act. Congress therefore directed the Secretary in the Act to review the scientific evidence for whether pertussis-containing vaccines can cause, among other conditions, autism:



51. The Act provided that the “Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the [required] study.” In implementing the foregoing congressional directive, the Secretary commissioned the IOM in 1989 to identify any and all medical and scientific literature addressing whether pertussis-containing vaccines can cause autism. <https://www.nap.edu/read/1815/chapter/1#v>. The IOM conducted this review and issued its report in 1991. *Id.* In that report, the IOM explained that it could not find any evidence to support the claim that pertussis-containing vaccines do not cause autism. *Id.* As explained by the

IOM, this is because “No data were identified that address the question of a relation between vaccination with DPT or its pertussis component and autism.” *Id.*

52. The following is a summary chart of the conclusions from the 1991 IOM report:

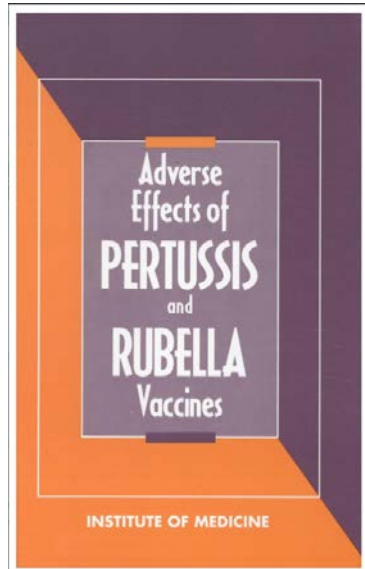


TABLE 1-2 Summary of Conclusions by Adverse Event for DPT^a and RA 27/3 MMR^b Vaccines

| Conclusion | Adverse Events Reviewed | |
|---|---|---|
| | DPT Vaccine | RA 27/3 Rubella Vaccine |
| 1. No evidence bearing on a causal relation ^c | Autism | |
| 2. Evidence insufficient to indicate a causal relation ^d | Aseptic meningitis Chronic neurologic damage Erythema multiforme or other rash Guillain-Barré syndrome Hemolytic anemia Juvenile diabetes Learning disabilities and attention-deficit disorder Peripheral mononeuropathy Thrombocytopenia | Radiculoneuritis and other neuropathies Thrombocytopenic purpura |
| 3. Evidence does not indicate a causal relation ^e | Infantile spasms Hypsarrhythmia Reye syndrome Sudden infant death syndrome | |
| 4. Evidence is consistent with a causal relation ^f | Acute encephalopathy ^g Shock and “unusual shock-like state” | Chronic arthritis |
| 5. Evidence indicates a causal relation ^h | Anaphylaxis Protracted, inconsolable crying | Acute arthritis |

53. Due to this and other shortcomings identified in the IOM’s report, the IOM committee explained in its 1991 report:

In the course of its review, the committee found many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. ... If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped.

<https://www.nap.edu/read/1815/chapter/9>.

b. In 2012, The IOM Again Reviewed Whether Pertussis-Containing Vaccines, including DTaP, Cause Autism

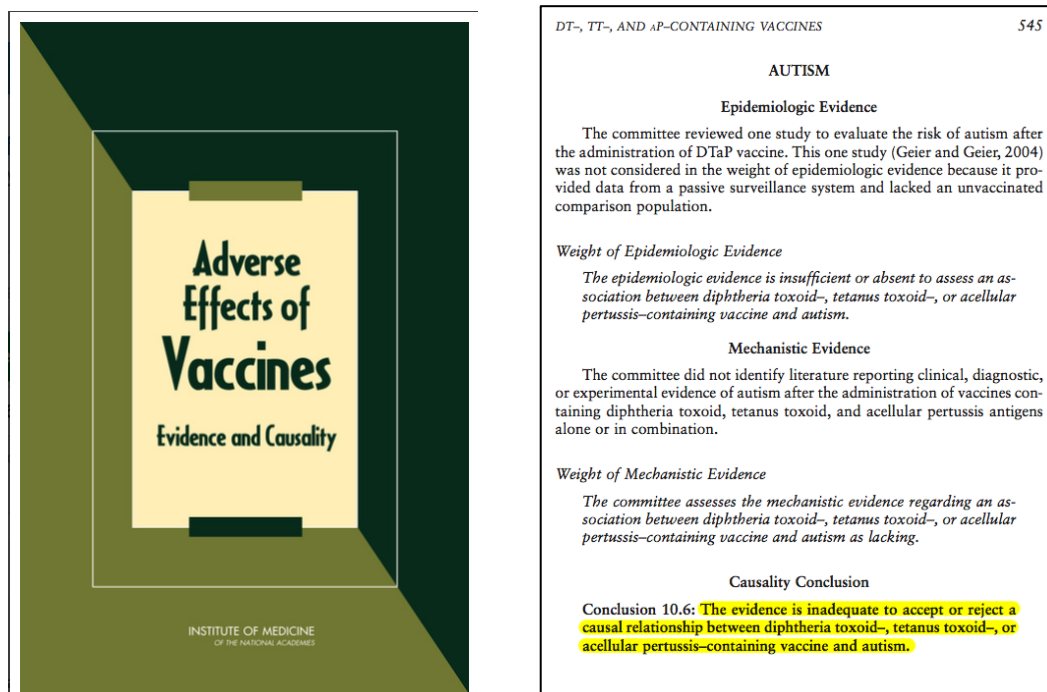
54. Nearly twenty years later, in 2012, the CDC and its sister agency, the Health Resources and Services Administration (“**HRSA**”), commissioned the IOM to again assess the evidence bearing on whether pertussis-containing vaccines, including DTaP, cause autism, as this

remained, according to the CDC and HRSA, one of the most commonly claimed injuries from this vaccine. <https://www.nap.edu/read/13164/chapter/2#2>.

55. The IOM convened a committee of experts to review the epidemiological, clinical, and biological evidence regarding adverse health events associated with specific vaccines. The committee was composed of individuals with expertise in pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law. <https://www.nap.edu/read/13164/chapter/1#v>.

56. Despite the intervening decades between the 1991 report and the 2012 report, the IOM's response to the CDC and HRSA in its 2012 report remained unchanged. The IOM could not locate a single study supporting the fact that DTaP does not cause autism. The IOM therefore concluded: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism." <https://www.nap.edu/read/13164/chapter/12#545>.

57. The following is the IOM's full explanation for this finding in its report:



58. The only study the IOM could locate regarding whether DTaP causes autism (Geier and Geier, 2004) concluded that there *was* an association between DTaP and autism. <https://www.nap.edu/read/13164/chapter/12?term=autism#545>.

c. In 2014, an HHS Agency Again Reviewed Whether Pertussis-Containing Vaccines, Including DTaP, Cause Autism and also Reviewed Whether Hepatitis B Vaccines Cause Autism

59. Just a few years after the 2012 IOM report was released, the Agency for Healthcare Research and Quality (“AHRQ”) again conducted a review searching for any study bearing on a potential causal relationship between pertussis-containing, tetanus-containing, and diphtheria-containing vaccines, including DTaP, and autism. https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf. HHS has explained that this report, published in 2014, represented “the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States.”

60. As with the IOM reports from 1991 and 2012, the “comprehensive review” published by AHRQ in 2014 again concluded that it could not identify a single study to support the claim that DTaP does not cause autism. *Id.*

61. This review also searched for studies that would support the claim that the Hepatitis B vaccine (given to babies at 1 day, 1 month, and 6 months of age) does not cause autism and also did not find a single study to support this claim. *Id.* Instead, the only study meeting its criteria for reliability was from the Stony Brook University Medical Center which found a 300% increased rate of autism among newborns receiving the Hepatitis B vaccine at birth compared to those who did not get this vaccine at birth. *Id.* The 2014 review summarizes the results of this study as follows:

Result was significant for the risk of autism in children who received their first dose of Hepatitis B vaccine during the first month of life

(OR 3.00, 95% CI 1.11, 8.13), compared with those who received the vaccination after the first month of life or not at all.

Id.

62. Having found one study that showed an association, and no studies to disprove this association, the review did not claim that the Hepatitis B vaccine does not cause autism. *Id.* Rather, it concluded it does not know whether the Hepatitis B vaccine causes autism. *Id.*

d. In 2017, the Chairman of the Interagency Autism Coordinating Committee Was Unable to Produce a Single Study to Support the Assertion that Vaccines Given to Babies Do Not Cause Autism

63. On May 31, 2017, the White House convened a meeting at the NIH in which the published agenda for the meeting included “Causes of autism, including genetic and environmental influences.” In attendance at that meeting were approximately a dozen individuals. Among them were two representatives from ICAN as well as:

- Dr. Francis Collins, Director (NIH)
- Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID)
- Dr. Joshua Gordon, Director, National Institute of Mental Health (NIMH) and, Chairman, Interagency Autism Coordinating Committee (IACC)
- Dr. Diana Bianchi, Director, Eunice Kennedy Shriver Institute of Child Health and Human Development (NICHD)
- Dr. Linda Birnbaum, Director, National Institute of Environmental Health Sciences (NIEHS)

64. During that meeting, Dr. Gordon, the Director of the National Institute of Mental Health and the Chairman of the Interagency Autism Coordinating Committee, asserted that vaccines do not cause autism. An ICAN representative asked him for the study which supports this conclusion. In response Dr. Gordon emailed the ICAN representative during the meeting a review of autism and MMR and thimerosal containing vaccines. The ICAN representative responded to Dr. Gordon by requesting a copy of any studies which support that the vaccines given

to babies – DTaP, Hep B, Hib, PCV13 and IPV – do not cause autism. Despite a multi-month exchange, including adding representatives from the CDC onto the email chain, in none of the emails from Dr. Gordon did he identify a single study to support the assertion that vaccines given to babies do not cause autism. The only studies provided were with regard to MMR vaccine (which is not given to babies) and/or thimerosal (not contained in any vaccines given to babies).

e. October 12, 2017 ICAN Demand to Secretary

65. Given the foregoing, ICAN sent a letter to HHS regarding vaccine safety, subscribed to by over 55 organizations whose members exceed 5 million Americans. A copy of this letter is attached as **Exhibit A**. This letter, in relevant part, provided:

Informed Consent Action Network hereby provides notice per 42 U.S.C. § 300aa-31(b). ...

As the Secretary of HHS (the Secretary), this means you shoulder virtually all responsibility for assuring the safety of vaccines administered to America's 78 million children.

This notice respectfully requests confirmation that certain obligations regarding vaccine safety required under the 1986 Act have been fulfilled or will forthwith be fulfilled. ...

Removing Claim “Vaccines Do Not Cause Autism” from the CDC Website

...As with DTaP, there are also no published studies showing that autism is not caused by Hepatitis B, Rotavirus, Hib, Pneumococcal, Inactivated Poliovirus, Influenza, Varicella, or Hepatitis A vaccines....²

Instead, [the CDC's] claim that “Vaccines Do Not Cause Autism” relies almost entirely upon studies exclusively studying only one vaccine, MMR (which is administered no earlier than one year of age), or only one vaccine ingredient, thimerosal, with regard to autism.³ ...

As for the MMR vaccine, the CDC's own Senior Scientist, Dr. William Thompson⁴, recently provided a statement through his attorney that the CDC “omitted statistically significant information” showing an

² <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>.

³ <https://www.cdc.gov/vaccinesafety/concerns/autism.html>.

⁴ Dr. Thompson has been a scientist at CDC for nearly two generations and a senior scientist on over a dozen CDC publications at the core of many of CDC's vaccine safety claims. <https://www.ncbi.nlm.nih.gov/pubmed>.

association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by the CDC with American children.⁵ Dr. Thompson, in a recorded phone call, stated...:

*I have great shame now when I meet families with kids with autism because I have been part of the problem ... the CDC is so paralyzed right now by anything related to autism. They're not doing what they should be doing because they're afraid to look for things that might be associated. So anyway there's still a lot of shame with that. ... I am completely ashamed of what I did.*⁶

Hence, as for the only vaccine, MMR, actually studied by the CDC with regard to autism, it appears the CDC may have concealed an association between that vaccine and autism.⁷

When the former Director of the National Institute of Health, Dr. Bernadine Healy, was asked about whether public health authorities are correct to claim that vaccines do not cause autism, she answered: "You can't say that."⁸ When asked again, Dr. Healy explained: "The more you delve into it – if you look at the basic science – if you look at the research that's been done, in animals – if you also look at some of these individual cases – *and*, if you look at the evidence that there *is* no link - what I come away with is: *The question has not been answered.*"⁹

Former NIH Director Dr. Healy goes on to explain:

This is the time when we do have the opportunity to understand whether or not there are susceptible children, perhaps genetically, perhaps they have a metabolic issue, mitochondrial disorder, immunological issue, that makes them more susceptible to vaccines plural, or to one particular vaccine, or to a component of vaccine... I haven't seen major studies that focus on - three hundred kids, who got autistic symptoms within a period of a few weeks of a vaccine. I think that the public health officials have been too quick to dismiss the hypothesis as irrational, without sufficient studies of causation. ...

The reason why they didn't want to look for those susceptibility groups was because they're afraid if they found them—however big or small they were—that that would scare the public away. First of all, I think the

⁵ <http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf>.

⁶ <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>.

⁷ Studies of MMR and autism are also erroneous because of healthy user bias, which has been emphasized as a serious source of error in epidemiological vaccine safety studies by CDC scientists. <https://doi.org/10.1093/oxfordjournals.aje.a116479>.

⁸ <http://www.cbsnews.com/news/the-open-question-on-vaccines-and-autism/>.

⁹ Ibid.

*public's smarter than that; the public values vaccines. But, more importantly, I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show!*¹⁰

The CDC has also failed to address the science supporting a link between vaccines and autism.¹¹ For example, the CDC has not addressed a study which found a 300% increased rate of autism among newborns receiving the hepatitis B vaccine at birth compared to those that did not.¹² Nor a recent and first ever vaccinated vs. unvaccinated pilot study which found vaccinated children had a 420% increased rate of autism and that vaccinated preterm babies had an even higher rate of autism.¹³ There is also a persuasive body of science supporting a clear connection between aluminum adjuvants in vaccines and autism which the CDC, despite numerous requests, has failed to directly or substantively address.¹⁴ Letters from three aluminum adjuvant experts on this point are attached as Appendix C.

The critical need for HHS to properly engage in vaccine safety science regarding autism is made even more vital by the fact that vaccine makers are immune from liability for vaccine injury and vaccines are not safety-tested prior to licensure to assess whether they cause autism. ...

Please confirm that HHS shall forthwith remove the claim that “Vaccines Do Not Cause Autism” from the CDC website, or alternatively, please identify the specific studies on which HHS bases its blanket claim that no vaccines cause autism?

....

We respectfully request your attention to the important concerns outlined above and hope you agree that addressing these concerns is in everyone's best interest. ...

If that is not possible, Congress, as a final resort to assure vaccine safety, authorized a “civil action ... against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under” the 1986 Act. ... It is, however, our hope that the vaccine safety issues identified herein can be resolved cooperatively, with all interested parties working together toward the common goal of vaccine safety entrusted to HHS under the 1986 Act.

¹⁰ Ibid.

¹¹ <https://www.cdc.gov/vaccinesafety/concerns/autism.html>.

¹² http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf.

¹³ <http://www.oatext.com/pdf/JTS-3-186.pdf>; <http://www.oatext.com/pdf/JTS-3-187.pdf>.

¹⁴ <http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf>.

f. On January 11, 2018, Dr. Stanley Plotkin Was Asked About Whether Studies Exist to Support that DTaP Vaccine Does Not Cause Autism

66. After sending the above letter, but before the Secretary responded, Dr. Stanley Plotkin, who is often referred to as “the Godfather of vaccinology” made an incredible admission under oath regarding vaccines and autism.

67. The equivalent of the Nobel prize in vaccinology is called the “Plotkin Award.” The medical textbook for vaccinology is called “Plotkin’s Vaccines.” The gavel used at the CDC’s Advisory Committee on Immunization Practices, which is the committee that decides the CDC’s childhood immunization schedule, is called the “Stanley A. Plotkin ACIP Gavel.” Dr. Plotkin has developed vaccinations for rubella, varicella, polio, rotavirus, rabies, and cytomegalovirus. Dr. Plotkin is the Founding Father of the Pediatric Infectious Diseases Society. He has published over 800 peer-reviewed articles, most of which relate to vaccinology. Dr. Plotkin has received over 50 awards and honors for his work in vaccinology, including the French Legion of Honor Medal, and is a member of the IOM.

68. There is arguably no scientist that has had a greater impact on vaccine policy at the CDC than Dr. Plotkin. A former member of the CDC’s Advisory Committee on Immunization Practices, Dr. Paul Offit, explained that Dr. Plotkin “trained a generation of scientists” involved in vaccine policy and advocacy “to think like he thinks.”

69. On January 11, 2018, Dr. Plotkin testified under oath in a litigation that had received national media attention. The following is an excerpt from that testimony:

Q What was the IOM’s conclusion in 2011 about whether [the DTaP and Tdap] vaccines can cause autism?

A I’d have to look that up, but I feel confident they do not cause autism.

Q ... This is an excerpt from the IOM’s report [from 2011], right?

A Yes.

Q ... If you take a look at that section please, was the IOM able to identify a single study supporting that DTaP and Tdap do not cause autism?

A No, they did not identify a study.

Q ... If you don't know whether DTaP or Tdap cause autism, shouldn't you wait until you do know, until you have the science to support it to then say that vaccines do not cause autism?

A Do I wait? No, I do not wait because I have to take into account the health of the child.

Q And so for that reason, you're okay with telling the parent that DTaP/Tdap does not cause autism even though the science isn't there yet to support that claim?

A Absolutely.¹⁵

g. January 18, 2018 Secretary Response to ICAN

70. The Secretary responded to ICAN's demand above regarding autism in a letter dated January 18, 2018, which provided as follows (a copy of this response is attached as **Exhibit B**):

Acting Secretary Hargan has asked me to thank you for your letter expressing interest in vaccine safety...

....

Many studies have looked at whether there is a relationship between vaccines and autism spectrum disorder (ASD). These studies continue to show that vaccines do **not** cause ASD. For more information, please refer to the literature below:

- <https://www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf>
- <http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx>
- [http://www.jpeds.com/article/S0022-3476\(13\)00144-/pdf?ext=.pdf](http://www.jpeds.com/article/S0022-3476(13)00144-/pdf?ext=.pdf)
<http://nationalacademies.org/HMD/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx>

While there is still a lot to learn about ASD, research from public and private organizations indicate that environmental and genetic factors may increase the risk of autism, not vaccines or vaccine ingredients. HHS continues to research this issue to search for answers to better understand the risk factors and causes of this disease. Recent efforts to coordinate autism research are reflected in the "Strategic Plan for Autism Spectrum Disorder Research" by the Interagency Autism Coordinating Committee at <https://iacc.hhs.gov/publications/strategic-plan/2017/>.

¹⁵ <https://www.youtube.com/watch?v=DFTsd042M3o>.

h. December 31, 2018 ICAN Response to the Secretary

71. Upon examination of the links provided by the Secretary in its response above, it is clear that none of these links contain a single study which supports the claim that the vaccines given to babies do not cause autism. As explained in ICAN's December 31, 2018 response, a copy of which is attached as **Exhibit C**:

Our opening letter ... asserted that, like the DTaP vaccine, there are also no published studies showing that autism is not caused by vaccines for Hepatitis B, ... Hib, Pneumococcal, Polio, [and] Influenza...¹⁶ HHS's response fails to provide a single study to rebut the foregoing. ... HHS has failed to address the science [ICAN cited] that does support a link between vaccines and autism.¹⁷ ...

Instead, HHS's response merely provides five links in response to our request for the studies supporting that pediatric vaccines do not cause autism. The content of these five links all directly reinforce and confirm the very concerns raised in our opening letter.

The *first* link is to a document entitled "Science Summary: CDC Studies on Thimerosal in Vaccines."¹⁸ The studies in this document are plainly insufficient to support the claim that "vaccines do not cause autism" as they at best only address whether thimerosal causes autism.

The *second* link is to an IOM report from 2004 entitled "Immunization Safety Review: Vaccines and Autism."¹⁹ This report also cannot support the CDC's claim about all vaccines because it *only* addresses the MMR vaccine and thimerosal with regard to autism. ...

The *third* link is a study which only looks at one vaccine component – antigens – comparing 'vaccinated children' with 'vaccinated children' with different antigen exposure.²⁰ This study again says nothing about whether any particular vaccine or HHS's childhood vaccine schedule causes autism. This study even concedes: "ASD with regression, in which children usually lose developmental skills during the second year of life, *could* be related to exposure in infancy, *including vaccines*."²¹

This antigen exposure study could have compared children receiving no-antigens, meaning no vaccines, with children receiving vaccine antigens. That would finally provide real data. Instead, the study engages in yet

¹⁶ <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>.

¹⁷ <https://www.cdc.gov/vaccinesafety/concerns/autism.html>.

¹⁸ <https://www.cdc.gov/vaccinesafety/pdf/cdestudiesonvaccinesandautism.pdf>.

¹⁹ <http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx>.

²⁰ <https://www.ncbi.nlm.nih.gov/pubmed/23545349>.

²¹ <https://www.ncbi.nlm.nih.gov/pubmed/23545349> (emphasis added).

another nonsensical whitewash review in which it compares vaccinated children with vaccinated children, with the only real difference typically being that some children received DTaP while others received DTP.²² All vaccines on the CDC childhood schedule, including DTaP, have been estimated to have between 1 and 69 antigens per dose while the DTP vaccine, no longer used in the U.S., is estimated to have 3,002 antigens per dose.²³ Hence, to compare antigen exposure, this study simply looks at one group of almost entirely fully vaccinated children who received DTaP with another group of almost entirely fully vaccinated children who received DTP. ...

This study further ignores the fact that while “antigens” (as defined in the study) in vaccines have decreased since the late 1990s, the amount of aluminum adjuvant, a neuro-and-cyto-toxic immune stimulant, used in vaccines has significantly *increased*. Indeed, in 1983 there was one aluminum-adjuvanted vaccine on HHS’s vaccine schedule, in 1998 there were three (Hep B, DTaP, Hib²⁴), and by 2018 the vaccine schedule included the following aluminum-adjuvanted vaccines: (1) Hep B, (2) DTaP, (3) Hib²⁵, (4) PCV13, (5) Hep A, (6) Tdap, and (7) HPV (and newer vaccines contain large amounts of aluminum adjuvant).²⁶ Also, the amount of aluminum adjuvant from Hep B, DTaP and Hib vaccines has increased since the late 1990s.²⁷ ... The antigen study HHS cites not only ignores the increasing amount of aluminum adjuvant included in childhood vaccines since 1999, it studiously ignores (as discussed below) the compelling body of science implicating this rising amount of aluminum adjuvant in vaccines with causing neurological dysfunction and autism.²⁸

But even putting all these limitations aside, this antigen study says nothing about whether any particular vaccine or group of vaccines cause autism, and, at best, relates to the potential connection between antigen exposure and autism (albeit in a study that, in its best light, is unreliable).

The *fourth* link HHS cites is the very IOM review ... cited in our opening letter.²⁹ However, as we noted in our letter, the IOM could not identify a single study which supports the claim that DTaP does not cause autism.³⁰ Even more astonishing, a different part of HHS’s response letter cites the 2014 “comprehensive review” which again could not identify a single study to support the claim that DTaP does not cause autism.³¹

²² <https://www.ncbi.nlm.nih.gov/pubmed/23545349>.

²³ <https://www.ncbi.nlm.nih.gov/pubmed/23545349>.

²⁴ In 1998, 1 out of 4 licensed Hib vaccines contained aluminum. Physicians’ Desk Reference, 1998, <http://www.pdr.net>.

²⁵ In 2018, 1 out of 3 licensed Hib vaccines contained aluminum. Physicians’ Desk Reference, 2018, <http://www.pdr.net>.

²⁶ <https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg>; <https://www.cdc.gov/mmwr/preview/mmwrhtml/00056261.htm>; <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>.

²⁷ Compare 1998 and 2018 editions of the Physicians’ Desk Reference. <http://www.pdr.net>.

²⁸ <http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf>.

²⁹ <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>.

³⁰ <http://nationalacademies.org/HMD/Reports/2011/adverse-effects-of-vaccines-evidence-and-causality.aspx>.

³¹ https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf.

HHS's 2014 review also searched for studies that would support the claim that the Hepatitis B vaccine does not cause autism and also did not find a single study to support this claim.³² In fact, [what it found was a study which] found a 300% increased rate of autism among newborns receiving the Hepatitis B vaccine at birth compared to those who did not get this vaccine at birth.³³ ... In short, the fourth link cited by HHS in fact proves, once again, that HHS cannot claim that vaccines do not cause autism.

The *fifth* (and final) link HHS cites in its letter is the "Strategic Plan for Autism Spectrum Disorder Research" by the Interagency Autism Coordinating Committee³⁴ Remarkably, this 196 page strategic plan outlines dozens of research priorities, but does not once mention closing the vaccine safety science gap regarding whether DTaP, Hepatitis B, and every other vaccine given by one year of age cause autism.³⁵

The strategy plan even explains that "neuroinflammation" may cause autism, but ignores the fact that neuroinflammation (a.k.a., encephalitis or encephalopathy) is a known reaction to numerous vaccines. For example, encephalitis or encephalopathy are listed as adverse reactions in the package inserts for the following vaccines injected multiple times into babies during their first few months of life: DTaP (Infanrix, Daptacel), Hepatitis B (Recombivax-HB, Engerix -B) and combination vaccines (Pediarix, Pentacel).³⁶ The strategic plan also recognizes "immune dysregulation" – which again can be caused by vaccines – may cause autism.³⁷ It also explains that current science suggests "that ASD results from subtle alterations during brain development [including during the first year of life] that affect brain structure, function and connectivity," which have been demonstrated to occur in lab animals following injection of comparable amounts of pediatric vaccines and/or aluminum adjuvants used in pediatric vaccines.³⁸

This strategic plan even outlines numerous large-scale studies looking at a plethora of environmental exposures, but apparently none of these include looking at the exposure to vaccines.³⁹ ... It would be simple to review vaccine exposures along with the hundreds of other exposures already being reviewed in these studies, but for apparently political reasons, HHS has chosen not to address this issue. ...

³² https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf.

³³ http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf.

³⁴ https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf.

³⁵ https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf.

³⁶ <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm124514.pdf>;
<https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm103037.pdf>;
<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf>;
<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf>;
<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241874.pdf>;
<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109810.pdf>.

³⁷ <https://onlinelibrary.wiley.com/doi/book/10.1002/9781118663721>.

³⁸ https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf; <http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf>.

³⁹ https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf.

HHS's Refusal to Study Vaccines-Autism Connection is Troubling

HHS has even remained silent and refused to seriously study the vaccine-autism connection despite the fact that HHS's leading autism expert, Dr. Andrew Zimmerman ... has changed his expert opinion.⁴⁰

Dr. Zimmerman is a former Director of Medical Research at the Center for Autism and Related Disorders at the Kennedy Krieger Institute and Johns Hopkins University School of Medicine, and is regarded as the leading national authority on autism...⁴¹ Dr. Zimmerman testified on November 9, 2016 that vaccines can in fact cause autism and even answered "Yes" when asked under oath: "Do other people in your field, reputable physicians in your field, hold the opinion that vaccines can cause the type of inflammatory response that can lead to a regressive autism?"⁴² Dr. Zimmerman further testified that once HHS understands and accepts the causal relationship between vaccines and autism, "it will prevent the development of autism in quite a few children."⁴³

Dr. Zimmerman's similarly credentialed colleague, Dr. Richard Kelley, also provided the following very revealing testimony ... under oath:

Lawyer: Do you agree with the statement that vaccines do not cause autism?

Dr. Kelley: No

Lawyer: Is it generally accepted in the medical community that vaccines do not cause autism?

Dr. Kelley: It is a common opinion.

Lawyer: It is generally accepted in the medical field that vaccines do not cause autism?

Dr. Kelley: I have no basis to judge that. It is most often when physicians are commenting on that they say there is no proven association.

Lawyer: Do you know the position of the American Academy of Pediatrics about any link between vaccines and autism?

Dr. Kelley: Yes. They also say there is no proven association.

Lawyer: Do you agree with the position of the American Academy of Pediatrics?

Dr. Kelley: I agree with their position as a public health measure. I don't agree with it scientifically.

Lawyer: You are actually arguing for a link between vaccines and autism in this case, aren't you?

Dr. Kelley: I am.

Lawyer: And that is contrary to the medical literature, isn't it?

Dr. Kelley: It's not contrary to the medical literature that I read. It is contrary to certain published articles by very authoritative groups who say there is no proven association in large cohort studies.

⁴⁰ https://childrenshealthdefense.org/child-health-topics/righting-wrongs/request-for-office-of-inspector-general-to-investigate-fraud-and-obstruction-of-justice/#_ftnref1.

⁴¹ <https://books.google.com/books?isbn=1603588256>.

⁴² <https://books.google.com/books?isbn=1603588256>.

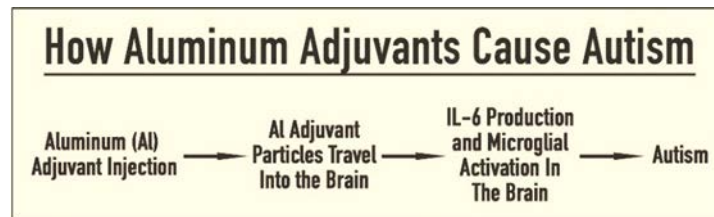
⁴³ <https://books.google.com/books?isbn=1603588256>.

Lawyer: Your opinion is contrary to, say, the opinion of the CDC, correct?

Dr. Kelley: It is contrary to their conclusion. It is not contrary to their data.⁴⁴

The view apparently held by HHS that “public health” demands hiding any relationship between vaccines and autism to assure high vaccine uptake, is troubling. This view (i) ignores the fact that the real “public health” emergency in the United States is that 1 in 36 children are now diagnosed with autism⁴⁵, (ii) stifles research into the association between vaccines on HHS’s childhood vaccine schedule and autism, and (iii) forces HHS to ignore any science that does support a vaccine-autism connection.

Indeed, HHS appears frozen when confronted with replicated peer-reviewed studies, many of which were funded by HHS, regarding immune activation and aluminum adjuvants that support a causal relationship between the receipt of vaccines containing aluminum adjuvants and the development of autism in children.⁴⁶ Our opening letter attached letters to HHS from world-renowned experts on the toxicity of aluminum adjuvants, each of whom strongly supported the contention that aluminum adjuvants may have a role in the etiology of autism and cited the body of science that supports their assertion.⁴⁷ This science reflects that: injected aluminum adjuvant is taken-up by immune cells (macrophages) at the injection site; these aluminum-adjuvant-loaded immune cells then travel through the lymph vessels to, among other places, the brain; the immune cells then unload their aluminum adjuvant cargo in the brain; and aluminum adjuvant in the brain causes a release of interleukin IL-6 and microglial activation, leading to autism.⁴⁸ Depicted in simple terms:



Despite years of vaccine safety advocacy demanding that HHS rebut, or at least address, the clear connection between aluminum adjuvant containing vaccines and autism, HHS appears unable to muster anything more than the public relations slogan – “Vaccines Do Not Cause Autism.”

On May 24, 2014, Dr. Thompson explained that the CDC is “paralyzed right now by anything related to autism ... because they’re afraid to look for things that might be associated.”⁴⁹ The reason for this fear may be that HHS has conceded or has been required by the Vaccine Court to pay financial compensation to at least a few dozen children where receipt of a

⁴⁴ <https://books.google.com/books?isbn=1603588256>.

⁴⁵ <https://www.cdc.gov/nchs/data/databriefs/db291.pdf>.

⁴⁶ <http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf>.

⁴⁷ <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>.

⁴⁸ <http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf>.

⁴⁹ <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>.

vaccine on HHS's childhood vaccine schedule resulted in brain, neurological and/or immune dysfunction diagnosed as autism.⁵⁰ The damage awards in some of these cases were in the millions of dollars.⁵¹ If a single study conducted by HHS shows that even 1 in 5 cases of autism are caused, directly or indirectly, by vaccines, it would result in approximately \$1.3 trillion in liability.⁵² Putting such potential liability into perspective, the entire federal budget in 2017 was \$3.3 trillion.⁵³ This and the decimation of HHS's reputation if it were found that certain vaccines cause a significant fraction of autism cases, provide powerful incentives for HHS to *not* fund the basic scientific research needed to determine whether HHS's childhood vaccine schedule is a cause of autism.

It is hard to imagine that HHS has not already internally used the databases at its disposal, such as VSD, to compare the autism rate between vaccinated and unvaccinated children. If the results showed no difference in the autism rates between these two groups of children, no doubt this study would have been published. The fact that it has not been published is very concerning. ...

HHS's approach to this issue ignores the tens of thousands of families across this country that have attested – often in videos available online – that their best judgment based on the totality of their parental experience with their child is that vaccination caused their child's autism. Numerous peer-reviewed studies have found that, when surveyed, between 40% and 70% of autism parents squarely blame vaccines for their child's autism.⁵⁴ Many of these surveys explain how parents express a clear personal experience with vaccination affirming this conclusion.⁵⁵

... [B]ased on available data and information, as discussed above, HHS cannot scientifically claim that "Vaccines Do Not Cause Autism." HHS must therefore remove this claim from the CDC website until it can produce the studies to support the claim that vaccines do not cause autism. ...

We await your response to each of the points raised above and the questions listed in Appendix A below.

⁵⁰ <https://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1681&context=pehr>.

⁵¹ <https://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1681&context=pehr>.

⁵² Since approximately 3.5 million American children have autism spectrum disorder and the approximate lifetime cost per individual is \$1.9 million, total cost of care for just 20% of these individual is \$1.3 trillion. www.autism-society.org/what-is/facts-and-statistics/.

⁵³ <https://www.cbo.gov/publication/53624>.

⁵⁴ <https://www.ncbi.nlm.nih.gov/pubmed/16685182>; <https://www.ncbi.nlm.nih.gov/pubmed/25398603>; <https://www.ncbi.nlm.nih.gov/pubmed/16547798>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/>.

⁵⁵ <https://www.ncbi.nlm.nih.gov/pubmed/16685182>; <https://www.ncbi.nlm.nih.gov/pubmed/25398603>; <https://www.ncbi.nlm.nih.gov/pubmed/16547798>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/>.

72. ICAN's response to the Secretary included an appendix which asked for an answer to the following question:

The following white paper provides the peer reviewed scientific support for how aluminum adjuvants injected into the body travel to the brain, can cause IL-6 production and microglial activation in the brain, and that this in turn can cause autism: <http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf>. Please clearly and specifically explain which steps in this chain of causation or any other aspect of this white paper HHS disputes.

i. June 21, 2019, Plaintiffs Submit a FOIA Request to the CDC for the Studies Relied Upon to Claim Vaccines Given to Babies Do Not Cause Autism

73. When the Secretary failed to respond to ICAN's letter of December 31, 2018, the Plaintiffs submitted a FOIA request on June 21, 2019 to the CDC seeking "All studies relied upon by CDC to claim that the DTaP vaccine does not cause autism." They made the same request for Hep B, Hib, PCV13 and IPV, as well as asking for the studies reflecting that, cumulatively, these vaccines do not cause autism.

74. When the CDC failed to produce a single study responsive to these requests, the Plaintiffs filed an administrative appeal on November 1, 2019. HHS acknowledged the appeal on November 14, 2019 but still failed to produce a copy of a single study responsive to the FOIA requests.

j. December 31, 2019, Plaintiffs File an Action to Compel the CDC to Produce Responsive Studies to their FOIA Requests

75. When the administrative appeal still did not produce any responsive studies, the Plaintiffs filed an action against the CDC to compel production of the studies it relies upon to claim that DTaP, Hep B, Hib, PCV13, and IPV, individually and collectively, do not cause autism. Since each of these vaccines are given three times during the first six months of life, without studies

supporting that they do not cause autism, the CDC cannot validly claim that vaccines do not cause autism.

76. A pretrial conference in this action was scheduled for March 2, 2020. *Institute for Autism Science, et al. v. Centers for Disease Control and Prevention*, No. 1:19-cv-11947-LJL Dkt. No. 5 (January 1, 2020, S.D.N.Y.). Leading up to this initial conference, the CDC provided the list of studies it relies upon to claim that DTaP, Hep B, Hib, PCV13 and IPV, individually and cumulatively, do not cause autism.

77. This list included 16 studies and 4 reviews conducted by the IOM. These 20 studies/reviews the CDC relies upon to claim that vaccines given to babies do not cause autism was memorialized in a stipulation entered into between the Plaintiffs and the CDC on February 28, 2020, and entered as an order of the Court on March 2, 2020. *Id.* Dkt. No. 15 (March 2, 2020, S.D.N.Y.). A copy of this stipulation and order is appended as **Exhibit D**.

78. Not one of these 16 studies and 4 reviews (*i.e.*, reviews of studies for a given research question) support the claim that vaccines injected into babies – DTaP, Hep B, Hib, PCV13, and IPV – do not cause autism. Instead, they include:

- 1 study concerning MMR (not a vaccine about which ICAN inquired);
- 13 studies concerning thimerosal (not an ingredient in any vaccine about which ICAN inquired);
- 3 reviews and 1 study concerning both MMR and thimerosal;
- 1 study concerning antigen (not vaccine) exposure; and
- 1 review concerning MMR, thimerosal, and DTaP.

79. Only one of the 20 studies/reviews identified by the CDC involved a vaccine given to babies – a 2012 review by the IOM, paid for by the CDC, which conducted a comprehensive review looking specifically for studies relating to whether DTaP does or does not cause autism. The IOM concluded that it could not identify a single study to support that DTaP does not cause autism. Instead, the only relevant study the IOM *could* identify found an association between

DTaP and autism. In other words, the only study/review out of 20 identified by the CDC that actually reviewed a vaccine given during the first year of life, DTaP, expressly found that there is not a single study to support the claim that it does not cause autism.

k. In March 2020, the Plaintiffs Provide the Secretary Additional Opportunities to Produce Studies to Support His Vaccine-Autism Claim

80. Dumfounded by the CDC's admission that it does not have a single study to support the vaccines given to babies do not cause autism, the Plaintiffs took two additional steps on March 10, 2020.

81. On March 10, 2020, ICAN sent a follow-up letter to the Secretary stating:

In our letter of October 12, 2017, we notified the Department of Health & Human Services (HHS) about a number of serious concerns regarding how HHS fulfills its obligations to ensure vaccine safety under the National Childhood Vaccine Injury Act of 1986 (the **1986 Act**).⁵⁶ ...

HHS responded to our letter in a reply dated January 18, 2018 [and] ... ICAN responded by letter dated December 31, 2018 ... [explaining] why HHS's reply ... either did not address or heightened the serious concerns raised in ICAN's prior letter...

It has now been over 13 months [and] ... HHS has failed to respond ... to ... the substance in that letter. ... Absent a substantive response to ... our December 31, 2018 letter within sixty days of this notice, an action against the Secretary of HHS shall be filed pursuant to 42 U.S.C. § 300aa-31.

82. In addition to sending the foregoing letter to the Secretary, to which the Secretary has still not responded, on March 10, 2020 the Plaintiffs also submitted another FOIA request to the CDC for "All studies supporting the claim that DTaP does not cause autism," in order to provide the CDC with yet another chance to provide the studies to support that vaccines given to babies do not cause autism. It did so by not only asking for studies the CDC "relied upon" to claim that DTaP does not cause autism, but for any studies that "support" that DTaP does not cause

⁵⁶ <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>.

autism. On March 23, 2020, the CDC responded to this FOIA request by pointing to the same list of twenty studies it previously pointed to in the stipulation and order of March 2, 2020.

83. On March 27, 2020, ICAN provided the CDC yet another opportunity to provide supportive studies by requesting via FOIA “Studies created or retained by CDC to support the claim that DTaP does not cause autism.” The CDC again responded by pointing to the same list of studies, all of which either relate to MMR or thimerosal, a single antigen (not vaccine) study, and one review by the IOM that looked for any support that DTaP does not cause autism and could not find a shred of such evidence.

I. August 27, 2020, the CDC Finally Removes Claim that “Vaccines Do Not Cause Autism” from its Website

84. On August 27, 2020, the CDC finally removed the claim that “Vaccines Do Not Cause Autism” from its webpage.

85. Nearly five months later, on January 21, 2021, ICAN widely publicized that the CDC had removed “Vaccines Do Not Cause Autism” from its webpage. Within days, the CDC restored this claim to its vaccine-autism page.

IV. Harm to Plaintiffs

86. The CDC’s vaccine-autism claim is used throughout the scientific, medical, and political landscape, and it drives research priorities, treatment options, and policy choices with regard to both vaccine safety research and autism research and treatments.

87. The CDC makes the claim that vaccines do not cause autism at www.cdc.gov/vaccinesafety/concerns/autism.html. The claim on this page is cited endlessly to deny any debate, research, and funding related to the question of whether vaccines cause autism.

88. The unsupported claim that vaccines do not cause autism has massive implications for the over 1 million children in the United States that already have autism and the 13.8 million

children expected to be diagnosed with autism in the coming five years assuming the rate of autism remains the same as it was in 2016 (which was 1 in 36 children, *see* <https://www.cdc.gov/nchs/data/databriefs/db291.pdf>).

89. Whether vaccines do or do not cause autism should be determined through scientific inquiry. But so long as the CDC claims, without the science to support same, that vaccines do not cause autism, the needed scientific inquiry will never receive the needed funding.

90. The Secretary's refusal to engage in the research needed to declare whether vaccines cause autism and his grant of permission to the nation's health agencies to claim that vaccines do not cause autism, without the requisite scientific support, creates concrete harms to Plaintiffs and is a direct violation of his obligation under the Act which provides, *inter alia*, that "the Secretary shall ... make or assure improvements in ... the licensing, ... testing, labeling, [and] warning, ... of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines" as well as "develop and disseminate vaccine information materials ... based on available data and information." 42 U.S.C. § 300aa-26 and 300aa-27.

91. ICAN is a leading national group focused on patient safety with regard to vaccines and its mission is to reduce the risks of adverse reactions from vaccines. To accomplish its mission, ICAN, among other things, identifies safety gaps in the literature supporting vaccine safety and supports scientists seeking to fill these gaps in order to reduce the risk of adverse reactions to vaccines. For example:

- Almost all FDA approved vaccines have been licensed based on clinical trials that did not include a placebo control group. <https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states>. ICAN therefore petitioned the FDA to require that the clinical trials for COVID-19 vaccines include a placebo control group.

- <http://tiny.cc/ao6vtz>. Thirteen days after filing this petition, the FDA required that all COVID-19 vaccines trials, which until that point had not included a placebo control group, henceforth include a placebo control group. <http://tiny.cc/po6vtz>. ICAN has filed additional petitions demanding greater safety and efficacy standards in the COVID-19 trials and greater transparency of the underlying data in these trials so that scientists can properly analyze the results of these trials. <http://tiny.cc/4p6vtz>; <http://tiny.cc/7p6vtz>; <http://tiny.cc/9p6vtz>; <http://tiny.cc/ep6vtz>; and <http://tiny.cc/hp6vtz>.
- Misinformation regarding vaccines can have serious consequences. ICAN therefore recently demanded that the New York State Department of Health and Governor Andrew Cuomo remove from their COVID-19 vaccines campaign the claims that these vaccines were “approved by the FDA, the CDC, and by NY’s independent vaccine panel.” <https://www.icandecide.org/wp-content/uploads/2021/02/Letter-to-NYSDOH.pdf>. ICAN also demanded it take down messaging that stated that “no serious vaccine side effects have been reported.” *Id.* In response, these false claims were removed by NYS. <http://tiny.cc/mp6vtz>. ICAN has made similar demands on other health departments across the country who have taken down similar false claims regarding the COVID-19 vaccines. *See, e.g.,* <https://www.icandecide.org/wp-content/uploads/2021/03/Letter-to-Michigan-DOH.pdf>. Removal of false claims regarding COVID-19 and vaccines is critical to assure that the needed science to actually support these claims are performed rather than bypassed since, by repetition, these false claims are eventually taken as true. ICAN has since petitioned the FDA to enforce its requirements under the emergency use authorizations granted for the COVID-19 vaccines. *See* <https://tinyurl.com/2a3dcr7s>.

- As another example, ICAN demanded the clinical trial reports for the two Hepatitis B vaccines given to newborns which reflect that they were licensed based on five days of safety review in their clinical trials. ICAN has received those documents for one of the vaccines and remains in an active litigation for the documents for the other vaccine. See <https://tinyurl.com/m7ptrv5e>; <https://tinyurl.com/ya6tb3cn>; <https://tinyurl.com/6d36rauk>; <https://tinyurl.com/b5se9wd8>; *Informed Consent Action Network v. United States FDA*, 1:20-cv-00689 (S.D.N.Y.). ICAN has petitioned the FDA to demand that a properly sized and controlled clinical trial of adequate duration be performed for these products. <http://tiny.cc/d37vtz>. Absent such data, there appears to be a serious lapse in the data supporting the safety of this product.
- ICAN has commenced actions seeking copies of the recommendations by the Task Force on Safer Childhood Vaccines and the biannual report to Congress that the Secretary is required to submit pursuant to section b and c, respectively, of the Mandate for Safer Childhood Vaccines codified at 42 U.S.C. § 300aa-27. These actions have brought to light the disturbing truths that the Task Force was disbanded in 1998 and the Secretary has failed to submit a single report to Congress detailing improvements in vaccine safety. ICAN is pushing for these actions to be taken, as required by federal law, in order to increase the safety profile surrounding the current childhood vaccine schedule.
- ICAN has filed over 400 Freedom of Information Act requests with HHS or its agencies, almost all of which relate to or are regarding vaccine safety and efficacy, in order to publish the data obtained so that scientists may work to increase the safety profile of the current childhood vaccine schedule. ICAN has also filed over 200 appeals and more than 10 actions with regard to these requests.

- ICAN has engaged with international agencies regarding various vaccine policies of concern including the UNICEF regarding its promotion and distribution of the DTP vaccine which well-designed and peer-reviewed studies have repeatedly shown increase mortality among children receiving this vaccine. See https://www.icandecide.org/government_category/united-nations-international-childrens-emergency-fund/.
- ICAN also supports research into vaccines and various safety concerns, including, for example, the relationship of aluminum adjuvants used in vaccines and autism as well as studies which use existing health data to retrospectively compare the health outcomes between vaccinated and unvaccinated children.

92. ICAN's vaccine work is aimed at reducing the risk of adverse reactions from vaccines. It works to achieve this goal by, among other things, identifying and publishing shortcomings with regard to the science underpinning claims of vaccine safety in order to promote additional research to fill research gaps. Filling these gaps will serve to increase the safety profile of childhood vaccines, either by providing assurance of safety or by identifying issues that should be corrected. Either way, the end result would be to increase vaccine confidence. The surest way to increase vaccine hesitancy and decrease vaccine confidence, however, is to make claims about vaccines without the science to support such claims.

93. One of the most common claims that ICAN's members and supporters have made and inquired about is with regard to vaccines and autism. ICAN, therefore, during the last four years, as detailed in this complaint, sought to obtain the studies that support the claim that vaccines given to babies do not cause autism. ICAN sought to publish the studies supporting this claim and to identify any gaps in the existing scientific body of work supporting the claim. To its amazement,

the science to support this claim is not merely deficient, it is entirely absent: there are no studies supporting the claim that vaccines do not cause autism with regard to the vaccines given to babies.

94. ICAN has sought for years to obtain research on the potential relationship between the vaccines given to babies and autism. During a meeting at the NIH arranged by the White House, two representatives from ICAN, its founder Del Bigtree and its legal counsel, the undersigned, were at the meeting, along with Dr. Francis Collins (Director of the National Institute of Health), Dr. Anthony Fauci (Director of the National Institutes of Allergy and Infectious Disease), and Dr. Joshua Gordon (Director of the National Institute of Mental Health and the Chairman of the Interagency Autism Coordinating Committee). During that meeting, counsel for ICAN directly asked if the leaders of NIH would use existing datasets available to them but not the public, such as the Vaccine Safety Datalink, which already includes thousands of completely unvaccinated children, to compare the health outcomes of those vaccinated with those that are unvaccinated. Such a study, which health authorities have never published, could provide useful data on whether vaccines given to babies cause autism. The NIH directors said they would not conduct such a study and instead relied on the claim by the CDC that vaccines do not cause autism, despite the fact that there are no studies to support this claim as to babies.

95. The urgent need to address whether vaccines are a cause of autism came into focus when federal health authorities heading the premiere agencies responsible for funding research on vaccine safety (the National Institute of Allergy and Infectious Diseases) and mental health (the National Institute of Mental Health) refused to perform the needed research. ICAN therefore engaged in the vaccine-autism letter exchange with the Secretary pursuant to 42 U.S.C. § 300aa-31 to demand this research, the vaccine-autism FOIA requests detailed above, and the legal action related to same detailed above. ICAN followed these actions by issuing a press release and public

posts regarding the deficiency in studying vaccines and autism in order to attract attention to this research gap and encourage science to fill this gap. The response should have been to encourage the needed science. Instead, ICAN was “fact checked” by Facebook through Health Feedback who said that is false to claim that the CDC does not have the science to support its claim that vaccines do not cause autism with regard to babies.

96. This widely distributed fact-check relied on one study to claim ICAN was wrong. That study, published in *Pediatrics*, was the same study cited in the Secretary’s letter, dated January 18, 2018, and which ICAN addressed in detail (as discussed above) in its response to HHS of December 31, 2018. In sum, that study, at best, can only address whether antigen (a certain vaccine ingredient) exposure can cause autism. It did not study whether a vaccine can cause autism. As this study even concedes: “ASD with regression, in which children usually lose developmental skills during the second year of life, *could* be related to exposure in infancy, *including* vaccines.”

97. Nonetheless, these fact checks eventually contributed to ICAN being removed from various social media platforms and therefore directly diminished ICAN’s ability to carry out its mission of identifying research gaps and promoting additional research to fill these gaps in order to reduce the risks of adverse reactions to vaccines.

98. The Secretary’s actions in making the unsupported vaccine-autism claim also directly harms ICAN in accomplishing its mission of disseminating accurate information about vaccines in order to reduce adverse reactions to vaccines. The Secretary has repeatedly told ICAN that vaccines do not cause autism even though the studies do not exist to make this claim for vaccines injected into babies. The Secretary has a duty to reduce adverse reactions to vaccines through research and ICAN has a mission to reduce adverse reactions by promoting gaps in vaccine

safety science to promote the research needed to reduce adverse reactions to vaccines. Unless the Secretary ceases making its claim that vaccines do not cause autism, at least until it has and can identify the science to make this claim for vaccines given to babies, ICAN cannot obtain the support or scientific participation needed to scientifically study this question.

99. Moreover, many of ICAN's members are pediatricians that are harmed by the Secretary making an unsupported claim regarding autism and vaccines given to babies. For example, Dr. Robert Sears is a practicing pediatrician whose practice includes vaccinating children. Many parents inquire with Dr. Sears about studies related to the vaccines that will be given to their babies in his practice. The research needed for him to adequately advise these parents regarding the risk of autism from vaccination for their babies is absent. This directly harms Dr. Sears' ability to properly advise his patients about the adverse reactions that may result from vaccination. Without studies, he cannot truthfully or ethically advise them that vaccines do not cause autism.

100. Many of ICAN's members and those it supports are also advocates for further research into vaccine safety, including numerous parents whose children had an adverse reaction to vaccination during the first year of life and developed autism, many of whom never received any other vaccines thereafter. For example, Brenda McDowell and David McDowell are the parents of three triplets that all developed autism shortly after a meningococcal vaccine during the first year of life and who gave an interview regarding their children's regression into autism from this vaccine and the improbability of being caused by anything other than the vaccine. An abridged three-minute version of the interview with the parents of these triplets is available at <https://www.youtube.com/watch?v=KN0qxO3G7eo> and the following is a transcription of a portion of this three-minute video:

Mother of the Triplets: We have triplets. Two boys and a girl: Richie, Robbie, and Claire. ... Every single day they were smiling and laughing and looking at each other and engaging in each other. On June 25th, 2007, we brought them in for the pneumococcal shot [Prevnar]. My daughter still has the mark on her leg from the shot. She was the first one to get it and she screamed and never really stopped screaming after that, but we continued, we didn't know. We did the boys, as well.

By noon, Claire shut completely off. It was as if she was blind and deaf, and all she did at that moment was stare at the ceiling. So that was at noon. We had the shot at 10 a.m.

At two o'clock, we watched Ritchie shut off. They lost all their reflexes. I'm an educational audiologist. I actually did the test for the stapedial reflex, which is a little muscle in the middle ear, just to see if a muscle they can't control was still working, and it didn't. The stapedial reflex dampens sounds, so your ears don't hurt from a really loud sound. And both of them had no stapedial reflex. They stopped blinking, stopped yawning, stopped coughing, stopped sneezing.

The worst was when we saw the final one shut down. Robbie, from that moment on, had a stunned look on his face. If you asked, or said his name, he still acted deaf, or acted like he couldn't hear. Although they did have normal hearing. I had it all tested. But he lost his happiness.

Three months after the shot, they were no longer engaged in anything or anyone. We were told it was genetic. And then we were told by geneticists that there is no possible way three children would shut off on the same day.

We had severe autism spectrum disorder for all three kids entering kindergarten. We have spent hundreds of thousands of dollars trying to recover them. The only person we got back was Robbie. The one that was last to shut off. Ritchie can only say single, maybe two, words together. Claire is still completely nonverbal, not potty trained. And Robbie is approaching grade level, but severe OCD.

Father of the Triplets: So, you've got, say a six-or seven-year-old child, who is not potty trained. And at two or three, four o'clock in the morning they fill their diaper. Well you can assume that pretty uncomfortable, so they take it off. Pretty soon it's all of them, it's all over the bed. In short order, it's all over me, it's all over her. I'm snapping at her, she's snapping at me. We are both snapping at the

kid who is the only innocent party in the whole scenario. And the one thing that is conspicuously absent from that scenario is anybody who told you that shot was safe. They are all asleep in their bed. They haven't got a problem in the world.

101. These parents are seriously injured by the lack of research confirming or rejecting that the vaccines given during the first year of life do or do not cause autism. Without this confirmatory research, their lived experiences are not only ignored, but derided. Their truth cannot be told without adverse consequences. Treatment options for their children will not be researched. The adverse events from the vaccine will find no remedy since the first step in fixing a problem is identifying its source.

102. Another member of ICAN is JB Handley whose child developed autism after vaccination. Handley is the author of *How to End the Autism Epidemic* and has directly supported helping tens of thousands of families with obtaining treatment for their child's autism. One of the worst harms he has seen is where one parent, typically the parent who took the child to the vaccine appointments, whose lived experience is that the vaccines caused a child's autism, ends up in a dispute with their spouse about the cause of the autism because of the CDC's assertion that vaccines do not cause autism. Accepting that vaccines could have caused the child's autism causes cognitive dissonance. JB Handley has personally witnessed numerous divorces directly resulting from one parent desperately clinging to and trusting the CDC's claim about vaccines and autism while the other remains resolute about their lived experience that the vaccines did cause their child's autism, at least until seeing studies showing otherwise.

103. This issue is common to the Plaintiffs. These groups support research into the causes of autism, including whether vaccines cause autism. Due to the CDC's declaration, researchers will not accept support from the Plaintiffs to study whether vaccines given to babies

cause autism. This prevents the needed research into vaccines and autism which is directly intended to reduce the potential risk of adverse reactions from vaccines.

104. The Plaintiffs also support research into the causes of autism in order to develop better treatments for autism. If vaccines are a cause of autism, knowing this would help develop better treatments for those so effected. Researchers will not accept support from the Plaintiffs because of the CDC's declaration that vaccines do not cause autism. This frustrates the research needed to assess the risk of autism from vaccines and to therefore address whether autism is a potential risk from vaccines given to babies.

105. Under the Act, the Secretary is mandated to ensure that the scientific community is performing "research on vaccines, in order to reduce the risks of adverse reactions to vaccines" as well as their "testing, labeling, [and] warning." Instead of performing the research to determine whether or not vaccines given to babies cause autism, the Secretary has instead stifled any such research from occurring by allowing the CDC to make the unsupported claim that vaccines do not cause autism, even though the CDC knows that it lacks support for that claim.

106. The Secretary is also obligated under the Act to produce Vaccine Information Statements ("VIS") "based on available data and information" for every childhood vaccine. The VISs are provided to parents prior to administering any vaccines. Each VIS informs these parents that additional relevant information regarding the vaccine is available at the CDC website, which in turn claims that "Vaccines Do Not Cause Autism." Because the Secretary has chosen to incorporate the CDC's website into the VIS as a resource, the information on that website regarding the relevant vaccine must, under federal law, be "based on available data and information." But, the available data and information, as discussed above, does not support the CDC's claim that "Vaccines do not cause autism." The Secretary must, therefore, remove this

claim from the CDC website until the agencies under his direction can produce the studies to support the claim that vaccines given to babies do not cause autism.

107. Plaintiffs, therefore, bring this action seeking a declaration that the Secretary has violated his duty under the Act by promoting a public relations slogan that all “Vaccines do not cause autism,” rather than relying on scientific evidence. This decision by the Secretary has caused direct harm, in varying ways, to each of the Plaintiffs, including by preventing the research needed to determine whether vaccines given to babies do, or do not, cause autism.

V. The Truth Matters

108. The CDC is seen as one of the most trusted authorities in the world with regard to vaccinations. Its pronouncements regarding vaccines impact policy, research, and funding priorities across all HHS agencies as well as research institutions in the United States and around the world. The Secretary should be able to support, with credible robust studies, the claims made regarding vaccine safety – especially for the vaccine safety issue it has claimed to have studied more thoroughly than any other claimed vaccine injury.

109. The most recent data from CDC reveals that 1 in 36 children born this year in the United States will have an autism diagnosis. This is a true epidemic. The CDC and health authorities have conducted a decades-long media campaign seeking to assure parents that vaccines do not cause autism. But making such statements without supporting studies is, at best, grossly irresponsible. Perhaps this is why a majority of parents of children with autism still assert, based on their lived experience and review of the primary sources, that it was one or more vaccines that caused their child’s autism. If the CDC and health authorities had spent resources on conducting the proper studies as required by the Act, rather than on media relations, perhaps they could produce the studies today which actually support this claim.

COUNT I
42 U.S.C. § 300aa-31

110. Plaintiffs restate and reallege all of the preceding paragraphs of this Complaint and incorporate them herein by reference.

111. Defendant Xavier Becerra is the Secretary of HHS.

112. The CDC is an agency within HHS.

113. The Secretary has asserted in letters to ICAN that vaccines do not cause autism.

114. HHS has asserted in publicly available sources that vaccines do not cause autism.

115. CDC has asserted in publicly available sources that vaccines do not cause autism.

116. The CDC's recommended childhood schedule includes the administration of, by six months of age, three doses each of DTaP vaccine, Hep B vaccine, PCV13 vaccine, IPV vaccine, and Hib vaccine, and one to two doses of IIV.

117. The CDC has on numerous occasions, including in a stipulation entered in the Federal District Court for the Southern District of New York, identified twenty studies/reviews that it claims constitute all of its support for its claim that vaccines do not cause autism.

118. None of the twenty studies/reviews identified by the CDC support that DTaP vaccine, Hep B vaccine, PCV13 vaccine, IPV vaccine, and Hib vaccine, and/or IIV vaccine do not cause autism.

119. There are no published studies which support the conclusion that Hep B vaccines do not cause autism.

120. There are no published studies which support the conclusion that the PCV13 vaccine does not cause autism.

121. There are no published studies which support the conclusion that the IPV vaccine does not cause autism.

122. There are no published studies which support the conclusion that the Hib vaccine does not cause autism.

123. There are no published studies which support the conclusion that the IIV vaccine does not cause autism.

124. Pursuant to the Act, the Secretary is required to “make or assure improvements in ... the licensing, ... testing, labeling, [and] warning, ... of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines” as well as “develop and disseminate vaccine information materials ... based on available data and information.” 42 U.S.C. § 300aa-26; 42 U.S.C. § 300aa-27.

125. The Secretary, along with the agencies he oversees, asserts to the public that vaccines do not cause autism, but neither the Secretary nor the agencies he oversees have the scientific studies necessary to make this claim with regard to vaccines given to babies (*i.e.*, under one year of age).

126. By disseminating, or allowing the agencies under his direction to disseminate, to the public and to Plaintiffs the claim that vaccines do not cause autism, the Secretary breached his duties under the Act, including but not limited to, his duty to only disseminate vaccine information based on data and information procured from scientific studies.

127. By disseminating for years the assertion that vaccines do not cause autism, while not conducting or financially supporting, or by not causing the agencies under his direction to conduct or financially support, scientific studies into whether the Hep B, PCV 13, IPV, Hib or IIV vaccines do not cause autism, the Secretary breached his duties under the Act, including but not limited to, his duty to develop vaccine information materials based on available data and

information procured from scientific studies and to conduct research to identify potential risks from vaccines in order to reduce adverse reactions from vaccines.

128. The Secretary's assertion, along with those of the agencies he oversees, that vaccines do not cause autism have and will continue to stifle the critical research needed to determine whether vaccines given to babies can be a cause or contributing factor of autism, including stifling funding for such research.

129. The Secretary's assertion, along with those of the agencies he oversees, have further caused direct material harm to Plaintiffs as detailed *supra* IV ¶¶ 89-109.

130. Because peer-reviewed scientific studies reflect that approximately forty percent of parents with a child with autism blame vaccines given before one year of age for causing their child's autism, the Secretary's unsupported assertion that vaccines do not cause autism also has ignored the pleas and cries of hundreds of thousands of parents over the preceding four decades that have collectively claimed that vaccines given to their babies were, based on their parental lived experience with their child, a cause of their child's autism.

131. Given the Secretary's forgoing violations of the Act, Plaintiffs respectfully request the declarations and order as detailed below in the requested relief.

REQUESTED RELIEF

WHEREFORE, Plaintiff prays that this Court:

a. Declare that the Secretary has violated his duties pursuant to 42 U.S.C. § 300aa-27 by asserting that "vaccines do not cause autism" without possessing scientific studies supporting that vaccines given to babies do not cause autism;

b. Declare that the Secretary has violated his duties pursuant to 42 U.S.C. § 300aa-26 by asserting that "vaccines do not cause autism" without possessing scientific studies supporting that vaccines given to babies do not cause autism;

c. Order that the Secretary shall henceforth remove, and cause all agencies under the Secretary's direct or indirect control to remove, from any public facing communications, the assertion that "vaccines do not cause autism" until such time as the Secretary can show to the Court's satisfaction that the Secretary possesses scientific studies that specifically support that the vaccines given to babies (*i.e.*, under one year of age) do not cause autism, however this order does not prohibit the Secretary, or any agencies under the Secretary's direct or indirect control, from making assertions that any specific vaccine does not cause autism, so long as the Secretary has scientific studies that specifically support the assertion that the specific vaccine at issue does not cause autism;

d. Award Plaintiffs their costs and reasonable attorneys' fees incurred in this action pursuant to 42 U.S.C. § 300aa-31(c) or pursuant to any statutory or common law right that permits for same; and

e. Grant such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts so triable.

May 8, 2021

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